UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:	)
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STAKEHOLDERS MEETING	)
MEETING WITH THE EDMONDS	)
INSTITUTE	)

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Training Room 1
4700 River Road
Riverdale, Maryland

Friday,
March 12, 2004

The hearing in the above-entitled matter was convened, pursuant to Notice, at 1:10 p.m.

BEFORE: JOHN TURNER
Director of Policy Coordination

APPEARANCES:

On Behalf of USDA/APHIS/BRS:

Chris Zakarka
Lee Handley
Craig Roseland
Michael Wach

On Behalf of The Edmonds Institute: (Via Phone)

Beth Burrows, President and Director

P R O C E E D I N G S

(1:10 p.m.)

MR. TURNER: I assume you're alone. There's no other people on the conference call?

MS. BURROWS: That's correct.

MR. TURNER: That's fine. Again, I'm John Turner. Cindy Smith was going to join us. She's our Deputy Administrator. Unfortunately, she went home ill. We do have several other people here and I can it's an impressive crowd, since you're not here to see them. You'll have to believe me.

MS. BURROWS: Could I be advised of who is there?

MR. TURNER: Sure. Again, I'm John Turner. My title is Director of Policy Coordination here in BRS, Biotech Regulatory Services.

MR. WACH: Beth, my name is Michael Wach and I'm an environmental protection specialist again with BRS.

MR. HANDLEY: I'm Lee Handley. I'm a risk assessor with BRS.

MS. ZAKARKA: Christine Zakarka with Policy Program Development.

MR. ROSELAND: Craig Roseland and I'm with the Policy Division.

MR. TURNER: Some of those may have been hard to hear.

MS. BURROWS: I heard I think five people.

MR. TURNER: Yes, that's it.

MS. BURROWS: Great. Okay. You're all in one way or another associated with USDA?

MR. TURNER: We're all at USDA. We're all in APHIS and we're all in Biotechnology Regulatory Services, except Chris Zakarka, who is with Program and Policy Development, PPD.

MS. BURROWS: Okay.

MR. TURNER: She's helping us with this process of the EIS.

MS. BURROWS: Great.

MR. TURNER: Here's how we can start. I'm going to give some opening remarks and background and then I'll turn it over to you.

You can give a statement or we can just have a give and take of discussions. However you want to proceed after that.

MS. BURROWS: Okay.

MR. TURNER: Welcome to our stakeholder discussion series on our upcoming environmental impact statement and revised plant biotech regulation. We want to thank you for taking time from your busy schedule to participate in this meeting and sharing your thoughts with us.

The purpose of these briefings is to: One, share

information regarding our plans to develop an EIS and amend our plant biotech regulations and two, gather a diverse, informative input which will support thoughtful and effective decision making on our part and the development of our new regulations.

We have here from BRS some of our management team and numerous members of our staff and when available, other key Agency personnel involved in supporting BRS may stop in.

I should also mention two key individuals who have been dedicated to providing full-time management of our work to complete both the EIS and our revised regulations. The first is myself, I'm John Turner. I don't know if we've met, but I've been around here a few years and I'm a familiar face to some. I'm going to be leading the effort.

The second is a new hire, Michael Wach. He's an environmental protection specialist with our new environmental and ecological analysis unit. In addition to possessing a PhD and an environmental law JD, Michael brings research experience in plant pathology and weed science, as well as legal experience working on cases involving NEPA, the Clean Water Act, the Clean Air Act and other environmental laws.

As you may know, we recently participated in inter-Agency discussions with EPA, FDA and the White House, which concluded that while the coordinated framework has

provided an appropriate science and risk based regulatory approach for biotechnology, the more recent Plant Protection Act of 2000 provides an opportunity for APHIS to revise its regulations and potentially expand our authority, while still leveraging experience we've gained through our history of regulation.

We concluded those discussions with general agreement on how our biotech regulatory approach would evolve. Still there's much opportunity for public and stakeholder input as we move forward to develop the specifics of our regulatory enhancements.

Given this, what we would like to do in these meetings is have an opportunity to hear your thoughts, as well as have an informal give and take of ideas and we have a unique opportunity now for this type of discussion, since we've not yet begun the formal rule making process.

So, we're free to speak openly and exchange ideas with stakeholders in the public. Our discussion today is being professionally transcribed for two reasons. First, we want an accurate record of our discussions to facilitate our ability to capture and refer to your input. Second, in the interest of transparency and fairness to all stakeholders, we will be making available as part of the public record and potentially on our website documentation of all our stakeholder discussions so that the public and

the other stakeholders will have the benefit of the discussions we will be conducting this week.

I want to emphasize that while we we're happy to share information on the direction we are likely to take during the process, that what we will be sharing is our current thinking in BRS and that during the process, public and stakeholder input will likely influence our thinking.

In addition, other officials within USDA, such as our Administrator, the Under Secretary, the Office of General Counsel and the Secretary can certainly be expected to provide insightful direction as well.

While we value all input, it is important for us all to recognize that our thinking will likely evolve. We may have some enthusiastic discussions today on a particular aspect of the regulations, but it will evolve over time.

Finally, since it is hard to predict exactly what the final regulation will look like, what we can share is our BRS priority areas, which will help us set direction.

The first of these is rigorous regulation, which thoroughly and appropriately evaluates and ensures safety and is supported by strong compliance and enforcement.

The second is transparency of the regulatory process and regulatory decision making to stakeholders and the public. This is critical to public confidence.

The third is we must have a science based system,

ensuring the best science is used to support regulatory decision making to assure safety.

The fourth is communication, coordination and collaboration, with a full range of stakeholders.

Fifth and finally is international leadership. We want to ensure that international biotech standards are all science based. We need to support international regulatory capacity building and we have to consider international implications of policy and regulatory decisions that we make.

So now as we begin our discussions, I'm going to turn it over to you and I would ask that you just state your name again before you start with any statements or discussion that you would like to begin with.

MS. BURROWS: Okay. My name is Beth Burrows, B-U-R-R-O-W-S. I am the President and Director of The Edmonds, E-D-M-O-N-D-S, Institute, which is a small public interest, nonprofit, 501(C)(3) organization, headquartered in Edmonds, Washington state.

We have a longstanding interest in bio safety and there are several issues that I will talk about, but I would first give you a little idea of what we do so that you will understand our perception of ourselves as stakeholders in this discussion.

The current emphasis of the Institute's work is on

bio safety and the legally binding international regulation of modern biotechnologies, as well as on intellectual property rights and just policies for the maintenance and protection of bio diversity, including policies and programs that foster recognition and sustenance of agricultural bio diversity and third, on the exploration of ethical implications of new technologies, including genetic engineering.

We have, since our inception in the mid 1990's, had a rather distinguished board of directors. We have always worked with pro bono scientists, by which I mean scientists that have worked for us on projects without any compensation.

The same is true of most of the lawyers and scholars we work with. We also work with some volunteers from the general public and we have close relationships with scientists, lawyers, scholars and activists around the world.

We are very much committed to sustaining the world's biological and cultural diversity, including its agricultural diversity and we are very proud to be that and insistent on remaining a small organization. We believe in walking our talk, so to speak and remaining sustainable.

Many years ago, when the United Nations convention on biological diversity started to talk about environmental

and human health effects of genetic engineering, The Edmonds Institute was among the first organizations to bring scientists to the discussion.

In that time period, in the early days, we quickly became concerned with the scientific quality of the discussion of bio safety and we were very fortunate in that we were able to put together a team of scientists who, over a period of a few years and after many, many iterations and a double blind peer review that was managed for us by a former head of the Ecological Society of America produced a two volume manual for assessing ecological and human health effects of genetically engineered organisms.

This is basically a manual that uses flowcharts and has a kind of forced choice inventory of questions that moves you through a flowchart. Often the answers are either yes or no. But the yes or no always involves a basis of research.

We have given away thousands of bound copies of the manual throughout the world. We have distributed copies on CD. We have produced videotape bio safety lectures to accompany them and to help naive users understand how to go through the assessment path of the manual using the flowcharts and the manual can currently be found, in downloadable form in PDF files on our website, the address of which is http://www.edmonds-institute.org.

We know from the number of hits on our site over the number of years that we've had it that really tens of thousands of copies have been downloaded. This is also a manual that is used in several bio safety trainings around the world and it's used in some universities in the United States to train students in bio safety.

Further, the Slovenian government saw fit to translate, to appoint a high level committee to translate that manual into Slovenian and the Slovenian version now resides on the website of their Department of Environment, that is of the Slovenian government.

A Russian translation has been done by an NGO, a non-governmental organization in Russia and currently a translator for the United Nations has been hired to check the Russian translation to assure that it's accurate and has not wavered from the original work of the scientists.

I want to mention the scientists involved, because they were not what I would call NGO scientists. Among them, in reverse alphabetical order, were: Dr. Mark Wheelis of the University of California-Davis, Dr. Andrew Spielman of Harvard School of Public Health, Dr. Philip Regal of the University of Minnesota, Deborah Letoureau of the University of California at Santa Cruz, Dr. Terrie Klinger of Friday Harbor Labs at the University of Washington, Dr. Anne Kapuscinski of the University of Minnesota, Dr. Conrad

Istock, formerly of the University of Arizona, Dr. Elaine Ingham, formerly of Oregon State University, Dr. Norman Ellstrand of the University of California at Riverside, Dr. Pushpa Bhargava of Anveshna Consultancy Services in India and Dr. Sharon Akabas of Columbia University.

I cannot stress enough how the making of that manual has influenced the position of The Edmonds Institute on all matters related to bio safety.

I strongly recommend that you go there and download copies. I know that in EPA and USDA, I think in FDA as well, there are people who have original copies that we distributed. Print copies that we distributed many years ago.

The reason I recommend you to go look at the manual is because it took a very long time to do and it was written to help people do bio safety or to help who seek for bio safety and in it you will see the kinds of questions and the kinds of things that we think appropriate to think about, in terms of bio safety, no matter what the organism, not matter what the product. I'll say no more than that. I could go on for hours alone talking about that.

The Edmonds Institute has also been involved, as I hinted at, in the work leading to the negotiations for the Cartegena Protocol on Bio Safety, which is a protocol of the convention on biological diversity.

We've been involved in expert and ad hoc expert working groups on a variety of areas from the bio safety clearing house through discussions of liability and excess in benefit sharing and so forth. We are convinced that whatever the USDA/APHIS should do, should be in keeping with that protocol, even though we do recognize that the United States is neither a party to the convention on biological diversity nor to the Cartegena Protocol on Bio Safety and at many key moments indeed played an oppositional role in the negotiations.

In particular, I would point people to the annex one and two of that protocol, which is available on the website of the convention on biological diversity as well as on the bio safety clearinghouse. The address of the website is www.biodiv.org, all lower case letters.

In looking at that website and considering all that we have done and I have not begun to tell you all the work of The Edmonds Institute, but I'm trying only to focus it on the bio safety related issues, I look at the sorts of things you're considering in scope and I have several things I would like you to consider.

One, the cost of the difficulty in understanding our laws, especially on the part of the public. It's an old saw by now, but it remains true that it is a patchwork of regulation and although from with inside the regulatory

agencies it may feel comfortable at this point, from without it does not and it is not transparent. It may be in some ways public, but not clear.

If you revise and expand authority, I think there should be something like our manual to help people understand by asking simple yes/no questions that have research implications, where any possible genetically modified, although certainly it could be in future dates changed for newer technologies, organisms fall within the ambits of all of the regulatory agencies.

I recognize this is not with USDA's doing, but for people to understand what you do, they also have to understand what the other agencies do and when something is and is not either or all of you.

When you started to say when you revise and expand your authority, you must make it clear as I would advise you to ask the other agencies to make clear there.

I would also enjoin all of the agencies to fill in the regulatory gaps. I think there were several issues that need to be dealt with. In particular, the question of monitoring. Not just a regulation, but monitoring over time, especially if you're thinking of deregulating, people would like to have a sense of what the data looks like. Not just the conclusions that you reach from the data, but how the data was gathered, what the data actually is and so

forth.

A question of confidential business information is also a salient question with the public and with The Edmonds Institute. It has to do with how regulation is transparent to the public. Although we understand that for some people the environmental and human health impact may seem to be confidential business information, to the public they're absolutely necessary information for transparency and you will never have our confidence in what you do as long as any part of the impact assessment is confidential business information.

We understand that you may not be able to change all regulations yourself. However, I feel it's my job as the head of a public interest group to sort of tell it like it is in terms of how it's perceived.

MR. TURNER: Beth?

MS. BURROWS: Yes?

MR. TURNER: On that note, we usually do environmental assessments or one thing that would trigger an environmental assessment for a lot of products is near the end when we deregulate. When it's time for commercialization. Is that mostly when you have the issue with the CBI or is it the same for notifications and field tests much earlier in the process or are they both?

MS. BURROWS: Depending on the organism, there

might be CBI concerns all the way along, starting with the right to know where it's being planted so that people in nearby places can monitor any unintended affects on their properties or on their bio diversity, that sort of thing.

However, certainly before it's commercialized, whatever basis there was or is for allowing the commercialization and saying such things as no significant impact, it would help the public to know what the data is that that decision is based on.

MR. TURNER: Okay.

MS. BURROWS: Again, I'm sorry. It would be much simpler for all of us if this were not complicated, but it is complicated and it is different for different organisms. Just like it's different in different ecosystems, which is another set of questions, when to deregulate, because a product may seem "safe" or safe-ish if you will in one ecosystem is not necessarily an indication that it will prove safe in all ecosystems.

Our manual is pretty much based on a case-by-case ecosystem-by-ecosystem approach and that seems to me a science based approach. Anything else actually is a socioeconomic base decision, when we seek to make decisions in one ecosystem based on what has happened in others. I don't believe that is a science based way of proceeding.

I do note that although USDA and others of the

agencies constantly talk about the wish for science based assessment, the impact assessment may be science based to some degree, but it is also socioeconomically based. How much will it cost to do this? How much can we afford to do this and so forth and so on?

The question of adventitious presence I would say is as much decided in the United States on the basis of socioeconomic considerations as on the basis of perceptions of science.

I think it's time to just say we take a lot of things into consideration when we make decisions about what we will allow people to plant or release.

I don't think the socioeconomic thing is something that is only used in the third world. I think it is something we in the United States take into consideration all of the time.

The question of adventitious presence, as I mentioned earlier, is important. It's important to consider what we mean by adventitious presence. How, if we set a level of tolerable adventitious presence, we will guarantee over time to keep that level and not allow it to rise slowly.

The question of estimating costs over time rather than at the moment of change. What I mean by that is this: The question of adventitious presence is often argued on

the basis of it would cost too much for us to separate variety A from variety B, whether in storage containers or on land or at sea or wherever.

Over time that cost diminishes and so I would like to see any kind of cost analyses done over time, together taking also into consideration projections of loss of market, should those separations not be made.

In looking at the notification that was put in the Federal Register, I notice the importance of definitions of all words. Almost all adjectives. I know this is extremely hard to do and in some ways the most contentious things to do.

There were word usages like minor and unresolved. I didn't know what was meant by them. I could guess, but they were only guesses.

I think you should put on every one of your committees, I'm sure you'll scream at this, but I would understand your screaming too I might say, put someone on your committees who doesn't know a heck of a lot about what you usually do so they can have the ability to ask you the hard questions that are very difficult to ask when you're a member of an agency over a long period of time.

Often this is a member of the public, but you need very special members of the public who have rather thick skin so that they can help you see what things are not

intuitively obvious or even reasonable.

Back to the question of particular engineered plants that we have particular concerns with, beyond our concerns with any of them. Those would be crops that are engineered to express pharmaceuticals or industrial chemicals or their precursors in their tissues.

We, at The Edmonds Institute, would argue that those crops must be grown under strict isolation and that isolation must be monitored from seed to after harvest.

Without long-term human health consumption and environmental safety studies, those crops cannot be allowed to be consumed, even under the most bizarre of circumstances, such as a hungry person passing a field, taking an ear of corn and going off to boil it without paying anyone or inquiring what it actually was.

If they're going to be grown indoors and if strict regulations are going to be put on all effluent and all waste from those facilities, we would have no problems with pharmaceutical crops. Our worry would happen, however, where they are grown anywhere else, especially outdoors.

We would posit that the risks from them are too great to take and that even in what would seem to be geographical isolation, there will always be a small possibility of some presence on the equipment, on the soles of feet including the feet of birds and so that if it is

ever contemplated to grow these out, there must be a whole cycle analysis that ensures, with very strict fines, that none of it ever finds its way into the food supply.

I'm trying to think if I've left out, probably I've left out many other things that we're concerned with, but you did say at the outset that this is a back and forth kind of thing.

Again, I would point you to our website. There is a listing of the publications that the Institute makes available. We'll be glad to make available whatever we still have in print and we'll be glad to share at least photocopies of the things that are out of print.

Do you have any questions for me? I've sort of rambled on and on and not in as good a manner as I had hoped, but there it is.

MR. TURNER: Anyone have any questions?

MR. WACH: This is Mike Wach. Beth, I had a couple of questions. One is probably a smaller question so I'll ask that one first.

You asked about doing ecosystem analysis in determining safety. I guess are you trying to characterize a farmer's field as being an ecosystem, because --

MS. BURROWS: A farmer's field doesn't exist all by itself. Yes, a farmer's field is an ecosystem. That's most definitely true. That is one ecosystem. Often a

farmer's field is adjacent to other ecosystems and what is planted there or what is grown there may have access to other ecosystems, which is another kind of analysis. I'm thinking in terms of fish farms kinds of things as well.

MR. WACH: Okay. Then the other --

MS. BURROWS: If you --

MR. WACH: I'm sorry.

MS. BURROWS: If you go and look at our manual, I mean I'm trying to do this over the phone, I don't have overheads --

MR. WACH: We actually have your manual right here on the computer.

MS. BURROWS: Okay. Great. Although the flowcharts look daunting, it's sort of graphic, when you realize how much to start through them and answer yes or no, depending on the questions, they're actually quite easy to go through.

But I emphasize the answers can't be guesses. In some cases they require a great deal of science and experimentation to determine the answer for particular crops. Go ahead. I'm sorry.

MR. WACH: The other question. I'm not sure if you actually answered it or if you left it as an open issue, but you said to fill in gaps in our regulations. Are the things you then enumerated are those what you perceive as

gaps or do you perceive additional gaps?

MS. BURROWS: I don't know if they're gaps. There are gaps in regulations or at least there are perceived gaps in regulations and I would like to see anything, for example anything that is genetically engineered to come under some regulatory scrutiny.

Depending on what it is, it might not be very heavy scrutiny, but it's not clear who has what power and not clear whether everything gets taken care of, given the way things are divided right now.

Over the years, we've always had in the NGO community, specialists to come and talk about the regulatory system in the United States or the regulatory system in Europe and so forth.

It's very difficult. It is not easy for people to understand the coverage. Who, for example, regulates genetically modified insects, if anyone? Who regulates by law fish and so forth?

I would like to see all of the possible taxa regulated, not necessarily by you. That's the other piece of it. That's why I've been hesitant to talk about it, because I think when you change your regulations and you have an environmental and ecological analysis unit, that's very nice, but that still creates confusion as to well, what does the EPA do and where does one begin and the other leave

off and are there places where neither gets and will there be places where both will be?

In the case of regulating the human ecology, the body, the human health consumption implications, it's not clear that anybody does the kind of studies that would give comfort to the people concerned about what those implications are.

I know FDA has that within its ambit and I'm trying to share with you perception, not necessarily your understanding, but the perception of many people in the public. Have I been more confusing than --

MR. WACH: No. You said there were gaps and then you mentioned several issues and I wanted to make sure that those weren't the gaps you perceive, but there were other things that you felt were gaps. I wanted to make sure that I got those out of you.

MS. BURROWS: Were there other questions?

MR. TURNER: Obviously we've heard you and we know you think we should close gaps and there are areas where you think probably more regulation is in order. Do you see any opportunities for us to regulate any areas less than we are now? Should we be involved with every movement of a genetically engineered organism, if it's from an academic lab-to-lab small amounts or do you think --

MS. BURROWS: Again, you're asking me questions

that are sort of black and white answers and my answer will be it depends on the organism. It depends on the environment. It depends on a whole lot of things and amount isn't necessarily the salient issue.

If it has a severe impact, you know two microbes may be too many. I think maybe the thing that would be more helpful for me to say would be it should be clear on what basis something is judged to be eligible to be deregulated. It should be clear what the process is that brings an organism or crop or whatever it is to a point where it may be considered for deregulation.

The process of adjudication should be transparent and it shouldn't be just a little paragraph: We're going to look into this, that and the other.

I would like to see the thinking laid out in that kind of flowchart way so that I, as a member of the public, can say, okay, they go through this and they ask this series of questions and the questions and the way they're laid out are based on scientific understanding at the moment of how things work.

Although we'll never get to perfectly safe or perfectly unsafe, we get closer to one or the other and at a certain point of closeness, things become eligible to be deregulated.

Then at that point, there's still a level of

monitoring and at another point further down the line, if it fulfills other standards or certain questions are answered, then even less regulation until there is none and always at any point there would be certain things that could start the whole process all over again, as in the case of an unforeseen event, an emergency that wasn't foreseen. A 20-year impact that took a very long time to see, because it was complicated and involved multiple species and so forth.

That kind of transparency would be extremely helpful. All of that would look horrible on paper. It would look like unending regulation, although in fact it would be a way to decrease regulation based on what I would call principles in reasoned scientific standards.

But unless that's transparent, unless all of us can know what that is and how it applies and how it has some safeguards in it and the it here is the decision making, it just won't feel comfortable to us. It won't feel reasonable. It won't feel scientific. It will always just feel political. Even ad hoc for that matter.

MR. TURNER: Would you see that type of long-term monitoring before the final input of total deregulation as being appropriate for every crop or on a case-by-case basis after --

MS. BURROWS: On a case-by-case basis.

MR. TURNER: -- assessment?

MS. BURROWS: Right, on a case-by-case basis. I mean I could imagine --

MR. TURNER: If there was the transparency and the laying out of the process, as you've --

MS. BURROWS: Right. Again, one of the reasons I liked the flowchart method is we didn't have to set standards for what we should worry about or what we shouldn't worry about.

If it went through and you came to the end, it was likely that you would decide to do it, decide to release or whatever or decide not to. It was all of those questions that gave the comfort, not the different standards.

I can imagine, for example, with some things the minute you find out one answer, you might very quickly go to a kind of deregulatory scenario. With other things that have other kinds of indications, you might go through a much more extensive regulation monitoring deregulation scenario.

It's the scenario you want. Obviously some part of USDA's clientele are farmers and agribusiness. If you show them something like our manual, they would faint because it looks like they're going to have to hire a thousand people to take care of it.

Then you can show with various crops, okay, let's look what really happens here and they can see with some varieties it might very quickly go to deregulation. With

other varieties it might never get out of regulation and monitoring.

That gets you out of the standard setting that you're going to constantly revise and just gives you a process.

MR. WACH: Beth, are you going to submit written comments?

MS. BURROWS: It had not been our intention to do so. Actually we sort of said, well we do one or the other. We really are tiny and we commented the other day on creeping bentgrass, which was not our intention to do either, but we chose to do it almost at the last moment.

MR. WACH: One thing I might suggest is that you submit your manual.

MS. BURROWS: Okay. I'm sitting here with the last print version of it. Can I submit it on a CD?

MR. WACH: I'm sorry. What?

MS. BURROWS: Does it need to be submitted in print?

MR. WACH: No, CD is fine.

MS. BURROWS: Okay. I have until the 20th. I can do that.

MR. WACH: 23rd I think. Isn't that correct?

MR. TURNER: I think so.

MR. WACH: The 23rd.

MS. BURROWS: Do I need to send multiple copies? I'm sorry.

MR. WACH: No, one is good.

MS. BURROWS: Again, does that go to Peter Fernandez? No. Who am I looking at here?

MR. WACH: It goes to Stephanie Stephens, right?

MS. BURROWS: Stephanie Stephens. Okay.

MR. WACH: Stephanie Stephens.

MS. BURROWS: Okay. Let me also say as I'm suggesting this manual, it is not and never was intended to be a cookbook written in stone. Some of the science has changed since it was written, but it will give you the idea. I need to say it is not a cookbook, but it is an indication of a way to think about the process.

MR. WACH: You said a couple things. First of all, you might want to indicate where it's being used. You mentioned a number of scientific experts who helped make it. You might want to indicate where it's being used.

MS. BURROWS: My goodness. I mean I can say with certainty a few universities, but where it's being used I would have to make assumption that the manuals that people tell me they used and found helpful are being used.

MR. WACH: Okay. That's fine.

MS. BURROWS: We didn't follow-up with surveys to see how it was used and whether people were being

forthcoming.

MR. TURNER: We don't want to be a burden. If you listed some of the examples that you're sure of.

MS. BURROWS: Okay.

MR. TURNER: It might be helpful. When you send it in, including the docket number is important, 03-031-2, but the instructions are on the front page of our proposed rule. The Federal Register notice of January 23, if you have that.

MS. BURROWS: Yes, I do have that.

MR. TURNER: That will give you the --

MS. BURROWS: I'm sorry we've run out of print copies. I did send tons and tons. We've sent them to various committees of the National Academy and so forth. I just don't have any more. I photocopied --

MR. WACH: That's okay, Beth. It's just that we can't submit it for you.

MS. BURROWS: No, I understand it.

MR. WACH: It's available to us on the web, but we can't submit it into the record on your behalf. You have to do it.

MS. BURROWS: Okay. Simply telling people where it resides --

MR. WACH: That doesn't count. Sorry.

MS. BURROWS: It doesn't count. Okay. Thank you

for that suggestion. I will do that.

MR. TURNER: Anyone else here have questions for Beth? Beth, do you have any other questions for us today?

MS. BURROWS: No. I actually don't quite see the point of me asking where you think the thing is going. I respect the fact that you're going to have to take a lot of testimony and comments into consideration and that it will change a great deal.

Rather than me getting all excited about something you might say today and then self-righteous about it later when you've changed your mind based on other testimony and other input, I think I'll wait to see what happens when you submit your suggestions later. That just seems to me a reasonable thing to do.

MR. TURNER: That's fair enough. As the process goes on, there's going to be more convergence so there will be other opportunities to comment and what we will have to comment upon will be more specific at those times.

We'll have a draft EIS, which you can comment on and at some point a proposed regulation I should say which you can comment upon. In terms of where it will go, all I will say is it is hard to say, but truly we're taking a broad look and we are considering all of the input and we will be considering a broad array of options.

MS. BURROWS: I welcome, I should have said that

at the open and I apologize for not doing so, I welcome the fact that USDA/APHIS is considering the possibility to revise their regulations. I think it would be more helpful if they could do it in tandem with the other agencies also considering revisions in their regulation.

It feels a bit like one member of a family making change and although that might be good in some senses, it will upset certain equilibria and possibly create other problems.

I would welcome, for example, another sort of grand meeting of all of the agencies, although I recognize that would be horrible for most of you. Just the logistics of it would be horrible, but that's probably what would be most useful.

Again, I think USDA/APHIS for doing this. I can't wait, because I do hope that whatever comes out will be improved and more clear, particularly to the public.

MR. TURNER: We hope so too and transparency is certainly a worthy goal.

MS. BURROWS: But transparency is not the same as clarity.

MR. TURNER: Transparent and clear. Clarity is important too. I guess what I'm saying is it's a good point that we agree with.

MS. BURROWS: Okay. I don't know what else to

say. I'm not prepared to say more at this point, but I am prepared to answer any questions you may have.

MR. TURNER: It looks like there are no more questions here.

MS. BURROWS: Okay.

MR. TURNER: You can certainly contact any of us if you think of additional things that would be helpful to you. Again, we thank you so much for taking the time to share your thoughts with us.

MS. BURROWS: Okay. Thank you.

(Whereupon, at 1:59 p.m., the hearing in the above-entitled matter was adjourned.)

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REPORTER'S CERTIFICATE

CASE TITLE: Biotechnology Regulatory Services

HEARING DATE: March 12, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: March 12, 2004

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